REMARKS

Applicants appreciate the withdrawal of the rejection made under 35 U.S.C. § 112; the sole remaining rejection is based on asserted anticipation by WO 02/28188 (Kern).

First, applicants believe that there is agreement on the law. Applicants acknowledge that although the disclosure of Kern is prophetic, actual reduction to practice is not required for anticipation. Applicants also agree that the patentability of product-by-process claims depends on the patentability of the product not the patentability of the process *per se*.

Applicants also believe that the Office agrees that legal precedent requires that the subject matter claimed to be inherently anticipated be the inevitable result of the processes described in the art. As quoted in the previous response:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Citing *In re Robertson*, 169 F3d 743, 745, 49 USPQ2d 1949, 1950-1951 (Fed. Cir. 1999).

Additional case law was provided in the previous response as well.

With these principles in mind, it becomes evident that Kern does not anticipate the present invention. There is no contention that Kern explicitly discloses, even prophetically, an immunocompromised mouse that has the characteristics of expressing a fluorescent protein in all tissues except hair and erythrocytes. Kern simply does not say that. The Office appears to assume that because Kern teaches that "the GFP transgene operatively linked to a constitutive promoter is present in the genome of every cell in the transgenic mouse, global expression would be an inherent characteristic of the mouse as constitutive promoters are not cell-specific and are capable of

expressing an operably linked coding sequence in all cells possessing a genome comprising the transgene."

Respectfully, this is not the case. Constitutive promoters are simply promoters which do not require the presence of an inducer. A "constitutive" promoter is not necessarily a "ubiquitous" promoter that is automatically operable in all cells. A "constitutive" promoter is continually "on." Cell-specialized promoters are also constitutive promoters and the use of a constitutive promoter does not lead to the inevitable result that all of the cells of the animal (that contain nuclei) will express the gene encoding fluorescent protein.

Applicants, on the other hand, have employed a murine source with a ubiquitous promoter driving expression. As noted in Example 1, the founder mice (C57B6-GFP mice) have the fluorescent protein under control of the chicken β-actin promoter. The β-actin promoter is a ubiquitous promoter and guarantees expression in all cells. Constitutive promoters do not. A constitutive promoter is defined as an unregulated promoter that allows continuous transcription of its cognate gene. It says nothing as to the ability of the promoter to be operative in all types of cells.

Since Kern fails to teach the use of a ubiquitously expressed promoter, expression of the fluorescent protein in all nucleated cells in the mouse is not "inevitable."

Assuming, therefore, that the basic legal principles are agreed upon, as an immunocompromised mouse that expresses a fluorescent protein in all tissues except hair and erythrocytes is not an inevitable result of the description set forth in Kern, no anticipation should be found.

In view of this, applicants believe the rejection may properly be withdrawn as to claims 1-3 and claims 19 and 20 rejoined. Passage of these claims to issue is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 312762004400.

Respectfully submitted,

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